

REMARKS

This responds to the Office Action mailed on October 17, 2007.

No claims are amended or canceled. Claims 27-29 are added; as a result, claims 1, 4, 7-22, 25, and 27-29 are now pending in this application.

§102 Rejection of the Claims

Claims 1, 4, 7, 13, 14, 20, 21 and 25 were rejected under 35 U.S.C. § 102(b) as being anticipated by US 6,060,085 to Osborne or US 5,863,560 to Osborne (as evidenced by Russell, AFP, 2000).

Osborne '085 is a continuation of Osborne '560. In order to simplify the arguments below, Applicant will refer only to Osborne, but the arguments apply to both Osborne '560 and Osborne '085. In addition, the Examiner appears to have mistakenly referred to the '085 patent as the '060 patent (beginning on page 3 of Office Action). Because there is no prior indication of any '060 patent and because the numbers before "085" in Osborne are "060," Applicant concludes that Examiner's '060 is meant to be the '085 Osborne patent. Applicant respectfully requests confirmation of this conclusion.

The Examiner has maintained the 35 U.S.C. § 102(b) rejection, concluding that both inflammatory and non-inflammatory lesions are inherent to the acne described in the teachings of Osborne and therefore the claimed method of reducing the number of non-inflammatory lesions and the treatment of non-inflammatory lesions of acne is inherent to the teachings of Osborne.

Applicant respectfully maintains the position that the Examiner's theory of inherency is misapplied. First, Applicant reiterates that the patent law on inherency relies on the fundamental, but not articulated, presumption of actual use. Because there was no actual use of Osborne's topical dapsone in treating conditions of any kind, Osborne does not inherently anticipate the use of dapsone in methods of treating non-inflammatory acne. Second, in the context of actual use, Applicant reiterates that anticipation cannot attach because the treatment of non-inflammatory acne would not necessarily occur each and every time the prior art dapsone were used to treat inflammatory acne. Applicant will further elaborate on these arguments below.

It remains Applicant's position that the patent law on inherency generally relies on a fundamental, but not articulated, presumption of actual use. As discussed previously, the case law (including *In re May*, *In re Crish*, *In re Best*, and *In re Cruciferous Sprout Litigation*) supports this position. Although anticipation was upheld in these cases, Applicant points out that the compositions or methods claimed in each instance had actually been used. In contrast, Osborne's topical dapsone was never actually used to treat any form of acne, nor any other ailment. The formulation was merely applied to the skin of cadavers to test its permeation and retention abilities; no conditions were treated by this application to the skin. It would thus be impossible for Osborne's method of use of dapsone to inherently treat non-inflammatory acne, since until the instant application dapsone had never before been applied to living skin for use in treating any type of ailment.

Additionally, because an inherent feature must be present every time the prior art method or composition is used (see Donald S. Chisum, CHISUM ON PATENTS § 3.03[2][b], 2006), it would be impossible to conclude that Osborne's topical dapsone could inherently treat non-inflammatory acne. An anticipation rejection that is based on inherency must be supported by factual and technical grounds establishing that the inherent feature must flow as a necessary conclusion, not simply a possible conclusion, from the teaching of the cited art. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Int. 1990); *In re Oelrich*, 666 F.2d 578, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981). The topical dapsone of Osborne was never actually used in treatment of inflammatory acne or any other skin condition; thus, it would be impossible for non-inflammatory acne to be necessarily treated each and every time the prior art dapsone were used, and inherent anticipation cannot attach. Applicant thus respectfully submits that inherent anticipation of the use of topical dapsone to treat non-inflammatory acne cannot be found without the real and necessary element of actual use in Osborne.

On pages 6-7 of the most recent Office Action, the Examiner responded to Applicant's actual use arguments by citing *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987) to support the position that Osborne's method of treating inflammatory acne with dapsone anticipates the claimed new use of treating non-inflammatory acne. Specifically, the Examiner states that *Gould* supports the conclusion that actual use is not required when a reference teaches the composition or method, and that inventions need not have actually been

reduced to practice prior to filing. Applicant respectfully argues that the Examiner's conclusion is incorrect, and points out that *Gould* applies only to enablement situations under 35 U.S.C. § 112, not to inherent anticipation situations under 35 U.S.C. § 102. *Gould* is cited in MPEP 2164.02, which is directed to working examples under the Enablement requirement (MPEP 2164). In *Gould*, the rejection was directed to enablement, not anticipation. Applicant has already stated that the issue here is not one of enablement, but rather one of actual use in inherent anticipation. Applicant and Examiner agree that Osborne's disclosure of the dapsone compositions and the use of dapsone to treat inflammatory acne are enabled. However, these enablement arguments do not apply to the analysis of actual use in inherent anticipation.

Applicant has added three new claims in this response. New claims 27-29 are supported in the specification by Example 2, page 4, paragraph [0045] and Table 1, page 4, right column. The example and table show the inverse relationship between treatment of inflammatory and non-inflammatory lesions with dapsone, where less dapsone applied less frequently causes better results in non-inflammatory acne, while more dapsone applied more frequently causes better results in inflammatory acne. Osborne does not teach or suggest these limitations present in claims 27-29. Applicant respectfully asserts that even if inherency is judged to apply, the inherency based upon Osborne does not include or suggest these parameters.

Thus, because Osborne's dapsone had never before been applied to living skin for use in treating any type of ailment and because of the inverse relationship between efficacy of treatment of inflammatory acne and non-inflammatory acne with dapsone, inherent anticipation of the claimed methods cannot be found. Applicant thus respectfully requests withdrawal of this rejection.

§103 Rejection of the Claims

Claims 8-12, 15-19 and 22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over US 6,060,085 in view of Russell, as applied to claims 1, 4, 7, 13, 14, 20, 21 and 25 above, and further in view of US 6,200,964 to Singleton et al. OR over US 5,863,560 ('560) in view of Russell, as applied to claims 1, 4, 7, 13, 14, 20, 21 and 25 above, and further in view of Russell and US 6,200,964 to Singleton et al.

The Examiner has maintained this rejection despite Applicant's arguments that the inherency issue was improperly carried over from the 35 U.S.C. § 102(b) rejection. The inherency doctrine has no place in the determination of the obviousness of a new use of an old compound (*In re Shetty*, 195 USPQ 753 (C.C.P.A. 1977) and *In re Dillon*, 13 USPQ2d 1335, 1348 (Fed. Cir. 1989)), and Applicant remains steadfast in the position that the treatment of non-inflammatory acne is not inherent to Osborne. Thus, the rejection under 35 U.S.C. § 103(a) is improper.

The Examiner has maintained the argument that the combination of references cited for the 35 U.S.C. § 103(a) rejection are not directed to the claimed method, but are instead directed to the claimed forms of the composition (i.e., cream, lotion, spray, etc.) and thus it would have been obvious to prepare the dapsone compositions of Osborne in these topical forms with an expectation to achieve the desired treatment of both types of acne lesions. Applicant respectfully disagrees with this conclusion.

Applicant contends that this is an improper rejection, because the claims at issue are method claims, not composition claims. In the rejected claims, Applicant is not attempting to claim the compositions themselves, but rather is claiming the methods using the compositions. Each of the rejected claims depends from claim 1, which recites a method for reducing non-inflammatory acne lesions with dapsone. Dependent claims include all of the limitations of the claims from which they depend (see MPEP 608.01(n)); thus, the method of treatment cannot be ignored in these rejections under 35 U.S.C. § 103. Additionally, the new claims 27-29 are also directed to methods of treatment, not compositions of matter. Applicant reminds the Examiner that the patentability of a new use for an "old" or known composition is a statutory mandate that has been relied on by the C.C.P.A. and the Federal Circuit. "See 35 U.S.C. § 101 (2000), identifying as patentable 'any new and useful improvements' of a process, machine, manufacture, etc); *In re King*, 801 F.2d 1324, 1326 (Fed. Cir. 1986) (principles of inherency do not prohibit a process patent for a new use of an old structure)." *Perricone v. Medicis Pharmaceutical Corp.*, 432 F.3d 1368, 1378 (Fed. Cir. 2005).

The only explanation provided by the Examiner regarding how Osborne, Russell and Singleton form the basis of the § 103 rejection is that Russell and Singleton disclose different skin types, creams, lotions, and sprays, so it therefore would have been obvious to prepare

dapsone in those formulations with an expectation to achieve the desired treatment of acne lesions (both types). The only way to reach this expectation of treating both types of acne lesions with dapsone is to implicitly carry the inherency conclusion over from the 35 U.S.C. § 102 analysis of Osborne. No other basis for the § 103 rejection of the claimed method of treating non-inflammatory acne is provided by the Examiner. As stated above, inherency is an improper basis for a 35 U.S.C. § 103 rejection.

As Applicant has previously shown, the only “expectation” a person of skill in the art would have regarding the treatment of non-inflammatory acne with dapsone is that it would not work. The references teach away from the claimed invention. Applicant again refers to the declaration of Robert Lathrop and the disclosure of Sykes in reiterating the well known fact that anti-microbials are counter-indicated for the treatment of non-inflammatory acne. Thus, the expectation to achieve the treatment of both types of acne with the topical dapsone of Osborne must result from the Examiner’s improper application of the inherency doctrine. Because the theory of inherency fails, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. § 103.

In summary, the Examiner has continued to rely on a theory of inherency for each of her arguments in rejecting the claims of the instant application. The entire case stands or falls on whether the dapsone of Osborne ‘085 and ‘560 inherently possesses the ability to reduce non-inflammatory acne. Applicant first submits that because the dapsone method of Osborne was never actually used to treat any kind of condition in a living being, this method cannot be said to inherently possess activity useful in the treatment of non-inflammatory acne. In the context of these arguments, Applicant additionally contends that because the treatment of non-inflammatory acne would not necessarily occur each and every time the prior art dapsone were used, anticipation cannot attach. Consequently, Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. § 102 and 35 U.S.C. § 103.

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.116 – EXPEDITED PROCEDURE

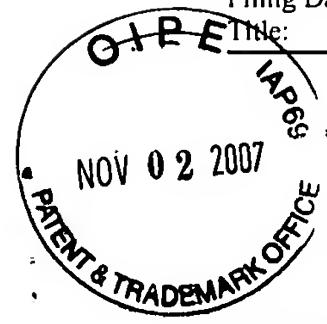
Serial Number: 10/081,050

Filing Date: February 20, 2002

Title: Topical Dapsone for the Treatment of Acne

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Dkt: 1195.346US1



CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 371-2106 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop RCE, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 31 day of October 2007.

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